

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

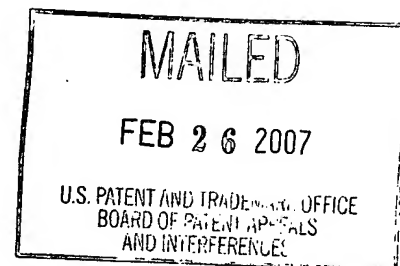
UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte JACK A. MAGGIORE
and BARBARA R. GRZEDA

Appeal 2006-2897
Application 10/074,715
Technology Center 1600

ON BRIEF



Before SCHEINER, GRIMES, and LINCK, *Administrative Patent Judges*.
LINCK, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the final rejection under 35 U.S.C. § 103(a) of the pending claims in the above-identified application, filed Feb. 13, 2002 and assigned to BioSafe Medical Technologies, Inc. We affirm.

STATEMENT OF THE CASE

The field of the claimed invention “relates to compositions and methods for stabilizing . . . biological fluid samples for analysis of protein analytes.” Specification (Spec.) at 1, ll. 5-7. “Biological fluid specimens are

preserved and stabilized for later analysis . . . with an aqueous biological fluid preserving composition containing a chelating agent and a . . . cell lysing agent.” *Id.* at 2, ll. 2-5. The compositions “can also include additives and adjuvants such as preservatives, antifreeze agents and non-chelating agents.” *Id.* They can also include “surfactants, and the like.” *Id.* at 3, l. 32.

Claims 12-18, 20-22, and 32 stand rejected. Appellants have not separately argued these claims. *See* Brief on Appeal (Br.) *passim*. Thus, the claims stand or fall together. Independent claim 12 reads:

An aqueous biological fluid preserving composition
suitable for lysing and preserving a blood sample for
hormone analysis, the composition consisting essentially of:

- a) about 0.05 to about 0.5 weight percent of a chelating agent;
- b) about 5 to about 25 weight percent of a cell lysing agent;
- c) up to about 0.1 weight percent of a preservative;
- d) up to about 50 weight percent of an antifreeze agent;
- and
- e) the remainder being water;

the composition being capable of preserving thyroid stimulating hormone present in the blood sample for at least about three weeks at an ambient temperature of about 22 °C.

The Examiner has rejected all the pending claims under 35 U.S.C. § 103(a) based on U.S. Patent Nos. 6,579,688 (Steaffens) and 5,616,460 (Figard).

ISSUES ON APPEAL

Relevant to claim 12, Appellants contend their claimed invention would not have been obvious in view of Steaffens and Figard because

(1) their claim language “consisting essentially of” excludes Steaffens’ serum protein and detergent; and (2) the cited references do not “teach or even suggest a composition that is capable of preserving thyroid stimulating hormone (TSH) in a blood sample for at least about 3 weeks at an ambient temperature of about 22 °C.” Br. 5.

The Examiner responds that the claim language “consisting essentially of” does not exclude Steaffens’ serum protein and detergent absent some showing they “would have affected the novel characteristics” of the claimed invention. Answer (Ans.) at 7. With respect to Appellants’ “being capable of” language, the Examiner contends Appellants have merely recognized “latent properties in the prior art composition” and such recognition “does not render nonobvious an otherwise known composition.” Final Office Action (mailed May 17, 2005) (FOA) at 11.

Given these contentions, the issue before us is as follows:

Would Appellants’ claimed preserving composition, “consisting essentially of” a chelating agent and a cell lysing agent and “being capable of preserving thyroid stimulating hormone” under the conditions recited in the claim have been obvious in view of Steaffens’ stabilizing composition comprising a chelating agent and a cell lysing agent?

FINDINGS OF FACT

I. The Invention

1. The specification describes the invention as follows:

“Biological fluid specimens are preserved and stabilized for later analysis . . . with an aqueous biological fluid preserving

composition containing a chelating agent and a . . . cell lysing agent.” Spec. at 2, ll. 2-5.

2. As broadly described, the invention may contain a “surfactant,” i.e., a detergent. *See id.* at 3, l. 32.
3. Also as broadly described, antifreeze agents and preservative agents are optional. *See id.* at 2, ll. 2-5.
4. Anti-microbial agents are one class of preservatives. *Id.* at 3, ll. 23.
5. A preferred preservative is sodium azide. *Id.* at 6, l. 13.
6. A particularly preferred antifreeze agent is ethylene glycol. *Id.* at 6, ll. 20-21.
7. “Biological fluid specimens that can be preserved” with Appellants’ compositions include “whole blood, plasma, serum” *Id.* at 4. *See also id.* at 11 (Example 3).
8. Serum would include serum proteins. *See, e.g.,* Steaffens, col. 4, ll. 19-21.

II. Claim Interpretation

1. Claim 12 requires: “about 0.05 to about 0.5 weight percent of a chelating agent” and “about 5 to about 25 weight percent of a cell lysing agent,” with “the remainder being water.” See claim 12 (quoted above).
2. “The term ‘chelating agent’ . . . means any chemical substance capable of chelating, complexing, or sequestering alkaline earth or transition metal ions [and] includes complexing agents and sequestering agents.” Spec. at 3, ll. 15-18.

3. The term includes EDTA, a preferred chelating agent. *Id.* at 5, ll. 19-20.
4. The “term ‘cell lysing agent’ . . . means any chemical medium or substance capable of disrupting the cellular membrane of cells in contact with the medium or substance . . . ,” *id.* at 3, ll. 10-13, and includes “water soluble organic solvents such as alcohols.” *Id.* at 4, l. 31 to 5, l. 1.
5. “A particularly preferred cell lysing agent is ethanol.” *Id.* at 5, ll. 3-4.
6. Claim 12 does not require either “a preservative” or “an antifreeze agent,” given that the language “up to . . .” indicates that none need be present. *See Ans.* at 6.
7. The claim language “consisting essentially of” does not exclude other components that do not materially affect the claimed composition. *See Ans.* at 7-8.
8. The claim language “being capable of preserving thyroid stimulating hormone” does not avoid prior art compositions that inherently possess this characteristic, even though it is not expressly disclosed. *See FOA* at 9-10.

III. The Cited Prior Art

1. Steaffens discloses stabilizing compositions containing a chelating agent and cell lysing agent (called a solubilizing or dispersing agent by Steaffens). *See, e.g.*, col. 4, ll. 33-53; col. 6, ll. 1-3 & 12-53.

See also Ans. at 4 (Steaffens provides “a cell lysing agent (dispersing), which is ethanol”); FOA at 5 (“ethanol” is “cell lysing or dispersing agent”).

2. Steaffens discloses amounts of chelating agents (0.1% to 30% v/v) and cell lysing agents (0.01 mM to 100 mM) that encompass or substantially overlap Appellants’ claimed ranges. Col. 6, ll. 31-34. *See also* Ans. at 7; FOA at 5.
3. Steaffens’ solubilizing agents include “alcohols such as ethanol,” one of Appellants’ preferred lysing agents. *See, e.g.*, col. 4, ll. 33-38.
4. Steaffens’ chelating agents include EDTA. *See, e.g.*, col. 6, l. 14.
5. Steaffens’ stabilizing compositions are “aqueous.” *See, e.g.*, col. 1, ll. 12-13.
6. While not required by claim 12, Steaffens also discloses a preservative in an amount overlapping the claimed range. *See, e.g.*, col. 4, l. 66-col. 5, l. 6; col. 6, ll. 1-3 & 12-53.
7. Figard discloses aqueous compositions for immunoassays, *inter alia*, “useful for stabilizing the immunoreactivity of antigens.” Col. 2, ll. 39-54.
8. Figard’s teachings are relevant to Appellants’ dependent claims and are not necessary to support the Examiner’s § 103(a) rejection of claim 12.

IV. Additional Findings

1. No evidence has been provided showing that Appellants' claimed ranges provide unexpected results over the ranges taught by Steaffens.
2. No evidence has been provided showing the additional components of Steaffens would materially affect the claimed invention.
3. No evidence has been provided showing Steaffens' compositions are not inherently "capable of preserving thyroid stimulating hormone."

APPLICABLE PRINCIPLES OF LAW

"[D]uring examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification." *In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000), *quoted with approval in In re Bigio*, 381 F.3d 1320, 1324, 72 USPQ2d 1209, 1210-11 (Fed. Cir. 2004).

The "claim phrase 'consisting essentially of' excludes ingredients that would 'materially affect the basic and novel characteristics' of the claimed composition." *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1574, 224 USPQ 409, 412 (Fed. Cir. 1984) (quoting *In re Herz*, 537 F.2d 549, 551, 190 USPQ 461, 463 (CCPA 1976)). Thus, the language "consisting essentially of" can include additional components that do not materially affect the basic and novel characteristics of the claimed composition. Appellants have "the burden of showing the basic or novel

characteristics” of their claimed preserving composition. *In re De Lajarte*, 337 F.2d 870, 874, 143 USPQ 256, 258 (CCPA 1964).

Relevant to the language “being capable of preserving thyroid stimulating hormone,” when prior art products and a claimed product are identical or only slightly different,

a rejection under 35 U.S.C. § 103 is indicated, and “the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product Whether the rejection is based on ‘inherency’ under 35 U.S.C. § 102, on ‘prima facie obviousness’ under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same (footnote omitted).” *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (Cust. & Pat. App. 1977). [*In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980).]

“A long line of cases confirms that one cannot establish novelty by claiming a known material by its properties.” *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004). When “the prior art evidence reasonably allows the PTO to conclude that a claimed feature is present in the prior art, the evidence ‘compels such a conclusion if the applicant produces no evidence or argument to rebut it.’ *Spada*, 911 F.2d at 708 n. 3.” *Crish*, 393 F.3d at 1259, 73 USPQ2d at 1369.

The “existence of overlapping or encompassing ranges shifts the burden to the applicant to show that his invention would not have been obvious.” *In re Peterson*, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1383 (Fed. Cir. 2003). *See also In re Woodruff*, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990).

ANALYSIS

The ultimate question before us is whether Appellants' claimed preserving composition, "consisting essentially of" a chelating agent and a cell lysing agent and "being capable of preserving thyroid stimulating hormone," would have been obvious in view of Steaffens' stabilizing composition comprising these two agents and additional components. The answer to this question depends upon our interpretation of claim 12, including its language "consisting essentially of" and "being capable of preserving thyroid stimulating hormone." The answer also depends upon our understanding of what the Examiner must show to make a prima facie case of obviousness.

Giving claim 12 its broadest reasonable interpretation, its preserving composition requires two components—"about 0.05 to about 0.5 weight percent of a chelating agent" and "about 5 to about 25 weight percent of a cell lysing agent" in an aqueous medium. Due to the language "up to," the recited the antifreeze and preservative agents are optional. Steaffens clearly discloses preserving compositions having a chelating agent and a cell lysing agent in amounts that encompass or overlap Appellants' claimed ranges. The language "consisting essentially of" excludes other components that materially affect the claimed composition. In each of Steaffens' embodiments, Steaffens includes additional components, i.e., a blocking

agent and a detergent. However, there is no evidence of record that these additional components would materially affect the composition of claim 12.¹

In this regard, Appellants' specification teaches that detergents ("surfactants") can be added, presumably without materially impacting the claimed compositions. Further, while Appellants argue that serum proteins (one of Steaffens' blocking agents) would raise "potential storage stability issues" (Br. at 6), the Examiner reasonably concluded that the antimicrobial preservatives used by both Steaffens and Appellants would address any such issues. *See* Ans. at 7. Thus, the Examiner reasonably concluded these additional components would not materially affect the novel and basic characteristics of Appellants' claimed composition. In such a situation, and given the difficulty the Office has in determining whether additional components would materially affect a claimed invention, the burden is on Appellants to make such a showing. They have failed to so do.²

The interpretation of claim 12 also requires us to consider the claim language "being capable of preserving thyroid stimulating hormone." The situation is analogous to that relating to "consisting essentially of." The Examiner reasonably concluded Steaffens' additional components would not materially affect the basic and novel characteristics of the claimed invention. It reasonably follows that Steaffens' compositions inherently would be

¹ Appellants argue these components are "important, as active ingredients," in Steaffens. Br. at 4. But that is not the test. *See the discussion supra* at pp. 7-8.

² Appellants further argue there is no teaching or suggestion "to omit the serum protein and detergent." Unless these components materially affect the claimed invention, which Appellants have not shown, their omission is not required.

capable of preserving thyroid stimulating hormone, as required by claim 12. Appellants have not adequately rebutted this conclusion.

Appellants also contend lack of motivation to combine the two references. The Examiner relies upon Figard primarily to address the limitations of the dependent claims. Thus, we conclude motivation to combine the two references need not be addressed, as the combination of Steaffens and Figard is not needed to address the limitations of claim 12.

CONCLUSIONS

The Examiner has made a prima facie case that Appellants' preserving composition of claim 12, "consisting essentially of" a chelating agent and a cell lysing agent, "capable of preserving thyroid stimulating hormone," would have been obvious in view of Steaffens' stabilizing composition comprising a chelating agent and a cell lysing agent. Appellants have not successfully rebutted the Examiner's prima facie case. Thus, we affirm the Examiner's rejection of claim 12.

Lacking any argument regarding their separate patentability, we also affirm the Examiner's rejection of the remaining pending claims 13-18, 20-22, and 32 under 37 C.F.R. § 41.37(c)(1)(vii).

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a)(1)(iv) (2004).

AFFIRMED



Toni R. Scheiner)
Administrative Patent Judge)



Eric Grimes)
Administrative Patent Judge)

) BOARD OF PATENT

) APPEALS AND



Nancy J. Linck)
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) INTERFERENCES

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